I. 7.2.2 Institutional Review Board Responsibilities

Chapter 7 - Research and Sponsored Programs	Original Effective Date: May 2008
Section: 7.2 Human Research Protection Program	Date Last Reviewed: June 2021
Responsible Entity: Vice President for Research	Date Last Revised: June 2021

II. Purpose

The University of Texas Health Science Center at San Antonio (UT Health San Antonio) has assured the Department of Health and Human Services (DHHS) of compliance with DHHS regulations (45 CFR § 46.103) for the protection of human subjects, through an Office of Human Research Protection (OHRP) approved Federalwide Assurance (FWA00005928).

III. Scope

When UT Health San Antonio (University) becomes engaged in research to which the FWA applies, the University and institutional review boards (IRBs) upon which it relies for review of such research will comply with the Common Rule. The FWA covers UT Health San Antonio, inclusive of the School of Medicine, the Dental School, the School of Nursing, the Graduate School of Biomedical Sciences, the School of Health Professions, centers, and organized research units.

IV. Policy

UT Health San Antonio established the IRB in accordance with the Handbook of Operating Policies (HOP) 1.6.6 Institutional Review Board. The University grants its IRBs the authority to:

1. Approve or require modifications to secure approval or disapprove all research activities overseen and conducted by the organization.
2. To suspend or terminate approval of research not being conducted in accordance with the IRB's requirements or that has been associated with unexpected harm or increased risk to participants.
3. To observe or have a third party observe, the consent process.
4. To observe, or have a third party observe, the conduct of the research.

5. To investigate allegations of non-compliance with institutional policies or research regulations for the protection of human subjects and reports of unanticipated problems. In cases where corrective action is needed, the IRB may take appropriate actions, to include, but not limited to, requiring modifications, determining data collected cannot be used for publication, suspending or terminating approval, requiring additional education, disqualifying investigators from conducting research involving human subjects at the institution, and recommending to the institution's administration that further administrative action be taken.
6. The IRB presents these determinations to the Institutional Official (IO), in whom ultimate approval authority is vested (ultimate approval authority for affiliated institutions relying on a UTHSA IRB is described in that institution's "Memorandum of Understanding" (MOU) with the University). Determination shall be presented in the form of IRB minutes presented for IO signature. The IO may accept, add additional restrictions to or reject some or all of the determinations of the IRB, with the exception that the IO cannot approve research involving human subjects that has not been approved by the IRB (e.g., tabled/deferred or disapproved by the IRB). Likewise, other officials or committees of the organization may not approve the research if it has not been approved by the IRB.

The authority granted to the UT Health San Antonio (UTHSA) IRBs is in accordance with the Protection of Human Subjects, Code of Federal Regulations (CFR), Title 45 Part 46 (45 CFR Part 46), 21 CFR Part 56 (and other applicable FDA regulations), and 38 CFR Part 16 (and other applicable VA regulations).

Where research includes information covered under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the IRB has authority to act as the Privacy Board to review, approve, require modifications in (to secure approval), or disapprove requests for alteration to individual authorization, waive individual authorization or partially waive required authorization for use or disclosure of protected health information as described in 45 CFR § 164.508.

A. Independence of the IRB

The University grants the IRBs the authority to act independently to bind all activities falling under the authority listed above. All University personnel who become aware of attempts to inappropriately influence the IRB are to report such incidents to the IRB Director of Research Protections Programs (RPP), who notifies the Assistant Vice President (AVP) for Research Administration and the IO (if allegations involve these individuals, the President will be notified). The IO in consultation with the AVP for Research Administration and the Director of RPP and other appropriate institutional officials will evaluate the allegation. If the allegation is validated, they will determine the appropriate response and any action required will be taken by at least a department level supervisor. Responses may range from an oral or written reprimand up to and including suspension of the individual from some or all current or future research

activities under the review of the UTHSA IRBs. The IO may refer the issue for additional institutional action.

B. IRB Policy Development

The Director of RPP develops and implements written IRB policies and procedures under applicable regulations for the protection of human subjects, in consultation with the VPR Executive Leadership.

C. Knowledge, Skills, and Abilities of Members

1. The IRB Chairs, members (primary and alternate) and Director of RPP and staff must be familiar with the ethical principles guiding human research; the requirements of federal regulations, applicable state law, the institution's FWA; and, institutional policies and procedures established for the protection of human subjects. The IRB as a whole must also have effective knowledge of subject populations and other factors which can potentially contribute to a determination of risks and benefits to subjects and which can impact participants' informed consent.
2. New members to the IRB shall receive orientation from the IRB Chairs, Director, or designee. Members must complete required training as outlined in applicable IRB education policies. Members will also receive continuing education on current topics of human research as outlined in applicable IRB education policies. Members are educated on topics, such as ethics, applicable regulations, policies, etc. Each member shall receive continuing education information as part of the IRB packets. Pertinent issues are discussed at meetings and documented in the minutes as appropriate.

D. Removal of IRB Members

Members may be disqualified from the IRB for scientific misconduct, unethical behavior, conflict of interest, or non-compliance with the rules governing the IRB or failure to actively participate. Such concerns are forwarded to the IO for review and action, as appropriate.

E. Meetings

IRBs meet regularly to review and act on initial and continuing review, as well as review of requests for modification of approved research, reports on non-compliance or unanticipated problems for all non-exempt human research. The Director of RPP establishes the schedule for meetings. The Director of RPP, Chair, or IO may direct or convene additional meetings at any time.

F. Affiliated Institutional Responsibilities

The UTHSA IRBs may provide review and continuing oversight of some or all research conducted at affiliated institutions through a valid signed IRB Authorization

Agreement Form. Institutions relying on the UTHSA IRBs remain responsible for ensuring compliance with the IRB's determinations and the terms of its OHRP approved FWA, as applicable.

Written procedures for reporting findings and actions to appropriate officials are documented in valid signed MOUs with institutions relying on the UTHSA IRBs for all or most of their research.

V. Definitions

There are no defined terms used in this Policy.

VI. Related References

There are no related documents associated with this Policy.

VII. Review and Approval History

The approving authority of this policy is the University Executive Committee.

Effective Date	Action Taken	Approved By	Date Approved
05/2008	Policy Origination		
05/2016	Policy Revision		
06/2021	Policy Revision		